Amendments to the Specification:

~~FIG. 2A is a top view of Microsampling device 20;~~

~~FIG. 2B is a sectional side view of device 20 of FIG. 2A across lines IIB-IIB, showing sample chamber 20C and chamber window 24W; and~~

~~FIG. 2C is a sectional and view of device 20 of FIG. 2A across lines IIC-IIC.~~ ~~Revise pages 6-9 of the specification as follows:~~

Fig. 2A is a perspective view of a microsampling device;

Fig. 2B is a top view of the microsampling device of Fig. 2A; and

Fig. 2C is a side view of the microsampling device of Fig. 2A.

Detailed Description of the Preferred Embodiments

The present invention comprises a process of constructing a cuvette window for a microsampling device for the measurement of biological materials from biological fluids. the microsampling device is preferably fabricated from a silicon wafer and is generally described in U.S. Patent No. 5,801,057, by Smart et al., the subject matter of which is hereby incorporated by reference in its entirety into this disclosure. Figs. 2A, 2B, and 2C, herein, depict the microsampling device of the '057 patent and are reproduced from Fis.1, 2A and 2B of the '057 patent. The same element numbers have been used Figs. 2A, 2B and 2C increased by 200 over the element numbers used in the corresponding figures of the '057 patent.

As shown in Fig. 2A, the microsampling device or microsampler of the present invention 210 has a very fine, short needle 211 through which blood or other body fluids can be drawn into a small sampling chamber (microcuvette) 212 which preferably has a volume of less than one microliter. Sampling chamber 212 has at least one optical window 213 and a vent 214 to allow air to escape as the camber fills when blood or other fluids are drawn in through needle 211. Needle 212 preferably has an outer diameter of 100 to 200 microns, compared to at least 425 microns for the smallest lancet currently available.

An exemplary design of microsampler 215 is shown in Figs. 2B and C. Needle 216 is formed as an etched channel (bore) 217 in silicon and sealed with glass cover 221 hermitically bonded to the silicon. The silicon body 218 contains a sampling chamber 219 from which needle bore 217 and vent 220 extend as an integral part thereof. The top of microsampler 215 is covered by cover glass 221 which forms an optical window for chamber 219 and also covers needle bore 217. Glass 222 deposited at the bottom of microsampler 215

forms a second optical window opposite optical window from camber 219. Glass 222 is deposited at the bottom of a depression 223 formed in silicon body 218.

Although the needle 216 may have an outer diameter in the range of 30 to 300 microns and a bore diameter in the range of 25 to 250 microns, in the exemplary embodiment, needle 216 has an outer diameter of 100 microns, a bore diameter of 50 microns, and a length of about 3mm. Silicon body 218 is about 5mm x 5mm square, and chamber 219 is about 2mm x 2mm square. Silicon body 218 has a thickness of about 500 microns to 1mm. Chamber 219 has a depth of about 50 microns and cover glass 221 has a thickness of about 150 microns.

The present invention has a transparent window on the silicon wafer to facilitate optical readouts of the specimen within the cuvette. Optical quality silicon nitride film is deposited on the silicon wafer and silicon removed such that a portion of the film is exposed on both sides.

The microsampling device or microsampler has a very fine, short needle though which blood or other body fluids can be drawn into a small sampling chamber or microcuvette. Preferably, the microcuvette has a volume of less than one microliter. The microcuvette has at least one optical window and a vent to allow air to escape as the microcuvette fills when blood or other fluids are drawn in through the needle. The needle preferably has an outer diameter of 100 to 200 micrometers.

The microsampler is constructed using well-established silicon microfabrication technology which has been in wide use for decades for the manufacture of electronic integrated circuits and more recently has been extended to micromechanical devices. The microsampler is made by a series of very precise photolithographic, etching and very precise microdeposition steps performed on a silicon wafer. A large number of the present microsampling device can be made at the same time on a single wafer, followed by dicing to separate the individual devices, each of which is commonly referred to as a die or chip in the microelectronics industry.

The cuvette window comprises a silicon nitride film formed on the microsampler chamber of the microsampler device with the window being exposed on two surfaces. The method of construction comprises providing a silicon wafer having a top surface 11S (sampling side) and a bottom surface 11v (viewing side), etching a patterned depression in the top surface of the silicon wafer thereby defining the microsampler chamber, depositing a silicon nitride film on the top surface of the silicon wafer, and etching a patterned depression

in the bottom surface of the silicon wafer such that at least a portion of the silicon nitride film deposited in the microsampler chamber becomes exposed on both surfaces.

The stages or steps of the cuvette window fabrication process are illustrated in Figs. 1A - 1D, and are described in further detail below. The microsampling device may have one or two cuvette windows, depending on the detection method used. A two window device suitable for [analyze] analyte detection using transmittance photometry can be fabricated from two wafers where the cuvettes and windows are bonded together in registration. Alternately, the second window can be provided separately in the device holder. A microsampling device with only one cuvette window is used where the methods of choice for the detection of the analyte may be fluorescence, luminescence, or reflectance photometry. In this case, a blank silicon wafer is bonded to the wafer containing the cuvettes and windows, and the individual devices then separated.

In the present example, a silicon wafer about 500 micrometers thick having one surface polished forms silicon substrate 10a of the microsampling device as illustrated in Fig. 1A. Silicon wafers of this type are commercially available and are commonly used in the integrated circuit industry in thickness of 500 to 1000 micrometers.

Silicon substrate 10a is first patterned and plasma etched on the top polished surface to form the vent, cuvette, and needle bore pattern required for operation of the microsampling device. Fig. 1B illustrates the microsampler chamber or cuvette in silicon substrate 10b subsequent to the plasma etching. As illustrated in Fig. 1C, low stress silicon nitride film 12c is then deposited onto the top surface of silicon substrate 10c. The silicon nitride film has a thickness of approximately 0.01 to 5 micrometers.

As illustrated in Fig. 1d, the bottom of silicon wafer 10d is then etched with a potassium hydroxide wet etchant to remove silicon and expose the bottom of silicon nitride window 12d.

~~Microsampling device 20 for obtaining a microsample of bodily fluid from a subject, is shown in FIG.s 2A, 2B, and 2C. Silicon substrate 20S has chamber 20C with sampling side 21S and viewing side 21V for containing and viewing the microsample (not shown). Chamber window 2rW formed of silicon nitride covers the chamber for closing the viewing side thereof. The silicon substrate may have a thickness of about 500 micrometers, and the silicon nitride window may have a thickness of from about 0.01 of a micrometer to about 5 micrometers, and the silicon nitride window may have a thickness of from about 0.01 of a micrometer to about 5 micrometers. The silicon nitride forming the window is preferably of optical quality. An antireflective coating of a suitable material such as magnesium fluoride~~

~~may be provided the silicon nitride window. Closure member 24C may be provided over the chamber for closing the sampling side. The closure member engages the substrate around the periphery of the chamber forming an interface there between. Needle 26N formed at needle and of 26 of the device may be provided for obtaining the sample. Intake bore 26B for transporting the sample into the chamber, extends from the needle end to the chamber along the interface between the closure member and the substrate. Exhaust vent 26V for venting the chamber as the sample is transported into the chamber, extends from the chamber away from the needle end along the interface between the closure member and the substrate. The bore and/ or the vent may be formed in the substrate.~~

Industrial Applicability

It will be apparent to those skilled in the art that the objects of this invention have been achieved as described hereinbefore by providing a silicon nitride cuvette window for a microsampling device. The silicon nitride window provides at least three advantages. First, the cuvette window can be fabricated by standard semiconductor processing methods. Second, the cuvette window is substantially transparent in the desired wavelengths. Finally, the cuvette window withstands normal handling in course of using the microsampling device.